

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION) MDL No. 2804
)
) Master Docket No. 1:17-md-2804
)
THIS DOCUMENT RELATES TO:) Hon. Dan Aaron Polster
)
<i>The Muscogee (Creek) Nation v. Purdue</i>) Individual Case No.
<i>Pharma L.P., et al.,</i>) 1:18-op-45459-DAP
<i>Case No. 1:18-op-45459-DAP</i>)
) JURY TRIAL DEMANDED

**DEFENDANT KVK-TECH, INC.'S FIRST AMENDED ANSWER AND AFFIRMATIVE
DEFENSES TO PLAINTIFF THE MUSCOGEE (CREEK) NATION'S
FIRST AMENDED COMPLAINT**

COMES NOW Defendant KVK-Tech, Inc. ("KVK-Tech"), by and through its attorneys of record, Baker Sterchi Cowden & Rice LLC, and submits its First Amended Answer and Affirmative Defenses to Plaintiff The Muscogee (Creek) Nation's ("Plaintiff" or "the Nation") First Amended Complaint.

PRELIMINARY STATEMENT

The following matters are incorporated by reference into the responses of KVK-Tech to each paragraph of the First Amended Complaint ("FAC").

A. KVK-Tech submits this First Amended Answer and Affirmative Defenses only on behalf of itself. As such, where allegations are made as against "Defendants" as a group, the responses of KVK-Tech apply only to KVK-Tech. To the extent the allegations of the FAC relate to Defendants other than KVK-Tech yet KVK-Tech is called upon to respond, KVK-Tech is without sufficient knowledge or information to form a belief as to the truth of the allegations and, therefore, denies all.

B. Except as otherwise expressly stated herein, KVK-Tech expressly denies each and every allegation contained in the FAC, including without limitation any allegations contained in Plaintiff's opening paragraphs, unnumbered paragraphs, headings, subheadings, and footnotes of the FAC, and specifically denies any liability to the Nation.

C. The FAC contains purported references to several documents and third-party publications and statements that have often been excerpted, paraphrased, characterized, and otherwise taken out of context. These third-party publications and statements should be considered, if at all, in context and in unmodified form, KVK-Tech hereby respectfully refers the Court to the respective third-party publications and statements for their complete contents.

D. The Nation's Lanham Act and Negligence Per Se claims have been dismissed by this Court and, therefore, no response is required from KVK-Tech and such claims must be disregarded. *See* 1:17-md-02804, Doc. Nos. 1499, pp. 47-50 (Report and Recommendation), 1680 (Opinion and Order). To the extent a response is required, KVK-Tech expressly denies all claims and allegations contained therein and reiterates the same further below.

E. In addition, to the extent the Nation's state-law claims depends upon allegations that the "Generic Manufacturers can correct the Brand-Name Manufacturers' alleged misrepresentations without violating the sameness principle," which would "impose upon the Generic Manufacturers liability for not sending warnings that the Brand-Name Manufacturers had not sent," such claims are preempted "because it would be impossible for the Generic Manufacturers to comply with both federal law and the supposed state law duty." (1:17-md-02804, Doc. Nos. 1499, pp. 34-42; 1680); thus, KVK-Tech incorporates by reference all applicable defenses available to it regarding preemption of Plaintiff's claims, and the Court's rulings finding preemption, into its First Amended Answers and Affirmative Defenses below. To the extent a

response is required, KVK-Tech expressly denies all claims and allegations contained therein and reiterates the same further below, but in no way waives the preemption defense found by the Report and Recommendation (Doc. No. 1499) and adopted by the Opinion and Order (Doc. No. 1680).

F. KVK-Tech expressly reserves the right to seek to amend and/or supplement its First Amended Answer and Affirmative Defenses as may be appropriate or necessary.

ANSWER

Incorporating the foregoing, KVK-Tech responds to the specific allegations of the FAC as follows:

No response is required to Plaintiff's opening paragraphs, including all subparts A-D, concerning who the Defendants are, the general claims and damages Plaintiff seeks, and the classifications by which Plaintiff will be referring to each Defendant (e.g. "Marketing Manufacturer Defendants," "Diversion Manufacturing Defendants," "Distributor Defendants," and "Pharmacy Defendants") inasmuch as these are not factual allegations contemplated by the Federal or Oklahoma Rules of Civil Procedure and/or state improper legal conclusions to which no response is required. To the extent a response is required, KVK-Tech denies the opening paragraphs, including all subparts A-D, of Plaintiff's FAC.

INTRODUCTION¹

1. In response to Paragraph 1 of the FAC, KVK-Tech admits that when used properly, prescription opioids can help manage pain for certain patients. KVK-Tech denies the remaining allegations directed against it contained within Paragraph 1 of the FAC directed against it that are inconsistent with what KVK-Tech has admitted.

¹ KVK-Tech does not make any admissions, and expressly denies, each and every heading and subheading listed throughout this First Amended Answer to the extent that inclusion of the headings would be deemed an admission of the same.

2. In response to Paragraph 2 of the FAC, KVK-Tech states that the statistics, studies, articles, and/or other authorities cited speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper. KVK-Tech denies the remaining allegations directed against it contained within Paragraph 2 of the FAC.

3. In response to Paragraph 3 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

4. In response to Paragraph 4 of the FAC, KVK-Tech denies the allegations directed against it, including an express denial of any engagement by it “in a massive marketing campaign” described therein, contained therein.

5. In response to Paragraph 5 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

6. In response to Paragraph 6 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

7. In response to Paragraph 7 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

8. In response to Paragraph 8 of the FAC, KVK-Tech denies the allegations directed against it contained therein, but otherwise states that no further response is required inasmuch as the allegations states legal conclusions to which no response is required.

9. In response to Paragraph 9 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

10. In response to Paragraph 10 of the FAC, KVK-Tech denies the allegations directed against it contained therein, but otherwise states that no further response is required inasmuch as the allegations states legal conclusions to which no response is required.

11. In response to Paragraph 11 of the FAC, KVK-Tech denies the allegations directed against it contained therein, but otherwise states that no further response is required inasmuch as the allegations states legal conclusions to which no response is required.

12. In response to Paragraph 12 of the FAC, KVK-Tech denies the allegations directed against it contained therein, but otherwise states that no further response is required inasmuch as the allegations states legal conclusions to which no response is required.

13. In response to Paragraph 13 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

14. Paragraph 14 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all

duties it has with respect to addressing diversion of its prescription opioid products, but denies the remaining allegations directed against it contained within Paragraph 14 of the FAC.

15. Paragraph 15 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein and further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

16. In response to Paragraph 16 of the FAC, KVK-Tech denies the allegations directed against it contained therein and states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

17. In response to Paragraph 17 of the FAC, KVK-Tech denies the allegations directed against it contained therein and states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

18. In response to Paragraph 18 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

19. In response to Paragraph 19 of the FAC, KVK-Tech denies the allegations directed against it contained therein and states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

20. In response to Paragraph 20 of the FAC, KVK-Tech denies the allegations directed against it contained therein, but otherwise states that no further response is required inasmuch as the allegations states legal conclusions to which no response is required.

21. In response to Paragraph 21 of the FAC, KVK-Tech denies the allegations directed against it contained therein, but otherwise states that no further response is required inasmuch as the allegations state legal conclusions to which no response is required.

22. In response to Paragraph 22 of the FAC, KVK-Tech denies the allegations directed against it contained therein and expressly denies that the Nation sustained the damages alleged as a result of defendant KVK-Tech, but otherwise states that no further response is required inasmuch as the allegations state legal conclusions to which no response is required.

23. In response to Paragraph 23 of the FAC, KVK-Tech states that while no response appears to be required to a statement for the types of claims the Nation purport to bring against it, to the extent a response is required, KVK-Tech denies the allegations directed against it contained therein and denies that the Nation has adequately pleaded any claim against it, or is entitled to any recovery against it.

24. In response to Paragraph 24 of the FAC, KVK-Tech states that while no response appears to be required to a statement for the types of relief the Nation purportedly seek, to the extent a response is required, KVK-Tech denies the allegations directed against it contained therein and denies that the Nation has adequately plead any claim against it, or is entitled to any recovery against it.

PARTIES

KVK-Tech reasserts and realleges all allegations contained within paragraphs 1 through 24 and in its Preliminary Statement, as if fully set forth herein and further alleges and asserts as follows:

I. PLAINTIFF

25. In response to Paragraph 25 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

26. In response to Paragraph 26 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

27. In response to Paragraph 27 of the FAC, KVK-Tech admits that the Nation is bringing this action against various Defendants, but specifically denies that the Nation has adequately plead any claim against it, or is entitled to any recovery against it. KVK-Tech further denies that it engaged in any “improper marketing, sales, distribution, dispensing, and reporting practices related to prescription opioids.” KVK-Tech states that as to the remaining allegations, if any, contained in Paragraph 27 of the FAC, it is without sufficient knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

II. DEFENDANTS

A. Marketing Manufacturer Defendants

28. In response to Paragraph 28 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

29. In response to Paragraph 29 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

30. In response to Paragraph 30 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

31. In response to Paragraph 31 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

32. In response to Paragraph 32 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

33. In response to Paragraph 33 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

34. In response to Paragraph 34 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

35. In response to Paragraph 35 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

36. In response to Paragraph 36 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

37. In response to Paragraph 37 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

38. In response to Paragraph 38 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

39. In response to Paragraph 39 of the FAC, KVK-Tech admits that it is a Pennsylvania business entity with its principal place of business is in Pennsylvania and that it is authorized to do business in the state of Oklahoma, but specifically denies that the Nation has adequately plead allegations sufficient to support the exercise of jurisdiction over this defendant or any claim against it, or is entitled to any recovery against it. KVK-Tech denies the remaining allegations of Paragraph 39 of the FAC.

40. Paragraph 40 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein.

B. Diversion Manufacturer Defendants

41. In response to Paragraph 41 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

42. In response to Paragraph 42 of the FAC, KVK-Tech admits that it is a Pennsylvania business entity with its principal place of business is in Pennsylvania and that it is authorized to do business in the state of Oklahoma, but specifically denies that the Nation has adequately plead allegations sufficient to support the exercise of jurisdiction over this defendant or any claim against it, or is entitled to any recovery against it. KVK-Tech denies the remaining allegations of Paragraph 39 of the FAC.

43. Paragraph 43 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein.

C. Distributor Defendants

44. In response to Paragraphs 44 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

45. In response to Paragraph 45 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

46. In response to Paragraph 46 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

47. In response to Paragraph 47 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

48. In response to Paragraph 48 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

49. In response to Paragraph 49 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

50. In response to Paragraph 50 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

51. In response to Paragraph 51 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of the allegations and therefore denies the same.

52. In response to Paragraph 52 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

53. In response to Paragraph 53 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

54. In response to Paragraph 54 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

55. In response to Paragraph 55 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

56. In response to Paragraph 56 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

57. In response to Paragraph 57 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

58. In response to Paragraph 58 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

59. In response to Paragraph 59 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

60. In response to Paragraph 60 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

61. In response to Paragraph 61 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

62. Paragraph 62 of the FAC calls for legal conclusions to which no response is required. To the extent a response is required, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

D. Pharmacy Defendants

63. In response to Paragraph 63 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

64. In response to Paragraph 64 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

65. In response to Paragraph 65 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

66. In response to Paragraph 66 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

67. In response to Paragraph 67 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

68. In response to Paragraph 68 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

69. In response to Paragraph 69 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

70. In response to Paragraph 70 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

71. In response to Paragraph 71 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

72. In response to Paragraph 72 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

73. In response to Paragraph 73 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

74. In response to Paragraph 74 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

75. In response to Paragraph 75 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

76. In response to Paragraph 76 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

77. In response to Paragraph 77 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

78. In response to Paragraph 78 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

79. In response to Paragraph 79 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

80. In response to Paragraph 80 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

81. In response to Paragraph 81 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

82. In response to Paragraph 82 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

83. In response to Paragraph 83 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

84. In response to Paragraph 84 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

85. In response to Paragraph 85 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

86. In response to Paragraph 86 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

87. In response to Paragraph 87 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

88. In response to Paragraph 88 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

89. In response to Paragraph 89 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

90. In response to Paragraph 90 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

91. In response to Paragraph 91 of the FAC, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

92. In response to Paragraph 92 of the FAC calls for legal conclusions to which no response is required. To the extent a response is required, KVK-Tech states it is without knowledge or information sufficient to form a belief as to the truth, matter, or intent, of those allegations and therefore denies the same.

JURISDICTION AND VENUE

KVK-Tech reasserts and realleges all allegations contained within paragraphs 1 through 92 and in its Preliminary Statement, as if fully set forth herein and further alleges and asserts as follows:

93. Paragraph 93 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech denies the allegations contained in Paragraph 93 of the FAC.

94. Paragraph 94 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech denies the allegations contained in Paragraph 94 of the FAC.

95. Paragraph 95 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech denies the allegations in Paragraph 95 of the FAC.

FACTUAL BACKGROUND

KVK-Tech reasserts and realleges all allegations contained within paragraphs 1 through 95 and in its Preliminary Statement, as if fully set forth herein and further alleges and asserts as follows:

I. PRESCRIPTION OPIOIDS ARE HIGHLY DANGEROUS

96. In response to Paragraph 96 of the FAC, KVK-Tech admits that when used properly, prescription opioids can help manage pain for certain patients. KVK-Tech denies the remaining allegations directed against it contained within Paragraph 96 of the FAC directed against it that are inconsistent with what KVK-Tech has admitted and further states that the statistics, studies articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

97. Paragraph 97 of the FAC calls for legal conclusions to which to no response is required. To the extent a response is required, KVK-Tech states that the cited statutes and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and otherwise denies any remaining allegations directed against it in Paragraph 97 of the FAC.

98. In response to Paragraph 98 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

II. MARKETING MANUFACTURER DEFENDANTS HAVE LEGAL DUTIES TO DISCLOSE ACCURATELY THE RISKS OF OPIOIDS

99. Paragraph 99 of the FAC calls for legal conclusions to which no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein.

100. Paragraph 100 of the FAC calls for legal conclusions to which no response is required and/or the statutory and/or other authorities cited speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein.

101. Paragraph 101 of the FAC calls for legal conclusions to which no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein.

III. MARKETING MANUFACTURER DEFENDANTS VIOLATED THEIR DUTIES

A. Marketing Manufacturer Defendants Made Misleading Statements About the Risks of Prescribing Opioids to Treat Chronic Pain and Failed to State Accurately the Magnitude of Those Risks

102. In response to Paragraph 102 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

103. In response to Paragraph 103 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

1. Marketing Manufacturer Defendants Misrepresented the Risks of Addiction to Prescription Opioids

104. In response to Paragraph 104 of the FAC, KVK-Tech denies the allegations directed against it contained therein. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

105. In response to Paragraph 105 of the FAC, KVK-Tech denies the allegations contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

106. In response to Paragraph 106 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

107. In response to Paragraph 107 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

108. In response to Paragraph 108 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the

statistics, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

109. In response to Paragraph 109 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

110. In response to Paragraph 110 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

111. In response to Paragraph 111 of the FAC, KVK-Tech denies the allegations directed against contained therein. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

112. In response to Paragraph 112 of the FAC, KVK-Tech denies the allegations directed against contained therein. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

113. In response to Paragraph 113 of the FAC, KVK-Tech denies the allegations directed against contained therein. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

114. In response to Paragraph 114 of the FAC, KVK-Tech denies the allegations directed against contained therein. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

115. In response to Paragraph 115 of the FAC, KVK-Tech denies the allegations directed against contained therein. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

2. Marketing Manufacturer Defendants Misleadingly Claimed that Patients Who Were Showing Signs of Addiction Were Not Actually Addicted

116. In response to Paragraph 116 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

117. In response to Paragraph 117 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

118. In response to Paragraph 118 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

119. In response to Paragraph 119 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

3. Marketing Manufacturer Defendants Falsely Claimed There Was No Risk in Increasing Opioid Dosages to Treat Chronic Pain

120. In response to Paragraph 120 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same.

121. In response to Paragraph 121 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

122. In response to Paragraph 122 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

123. In response to Paragraph 123 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

124. In response to Paragraph 124 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

125. In response to Paragraph 125 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the

statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

B. Marketing Manufacturer Defendants' Misleading Statements Were Designed For Maximum Effect and Targeted to Specific Audiences

126. In response to Paragraph 126 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same.

127. In response to Paragraph 127 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same.

128. In response to Paragraph 128 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

129. In response to Paragraph 129 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

130. In response to Paragraph 130 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same.

131. In response to Paragraph 131 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

132. In response to Paragraph 132 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

133. In response to Paragraph 133 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

134. In response to Paragraph 134 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

135. In response to Paragraph 135 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same.

136. In response to Paragraph 136 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

137. In response to Paragraph 137 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

C. Marketing Manufacturer Defendants Knew or Should Have Known That Their Statements Were Misleading

138. In response to Paragraph 138 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same.

139. In response to Paragraph 139 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

140. In response to Paragraph 140 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

141. In response to Paragraph 141 of the FAC, KVK-Tech states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

142. In response to Paragraph 142 of the FAC, KVK-Tech has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

143. In response to Paragraph 143, including all subparts (a)-(c) of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

144. In response to Paragraph 144 of the FAC, KVK-Tech denies the allegations directed against it contained therein and further states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

145. In response to Paragraph 145 of the FAC, KVK-Tech states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited

therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

146. In response to Paragraph 146 of the FAC, KVK-Tech states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

147. In response to Paragraph 147 of the FAC, KVK-Tech states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

148. In response to Paragraph 148 of the FAC, KVK-Tech states that it has no knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein related to other named Defendants therein, and therefore, denies the same. KVK-Tech further states that the statistics, studies, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

D. Marketing Manufacturer Defendants' Conduct Violated Their Duties

149. In response to Paragraph 149 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

150. Paragraph 150 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein.

151. In response to Paragraph 151 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

E. The Nation Was Harmed by Marketing Manufacturer Defendants' Name-Brand Prescription Opioids and Their Generic Equivalents as a Result of Defendants' Wrongful Marketing Conduct

152. In response to Paragraph 152 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

153. In response to Paragraph 153 of the FAC, KVK-Tech admits that pharmacists may, with a doctor or patient's consent, substitute a generic equivalent of a name-brand prescription medication for that of a generic prescription medication and that such actions are governed by specific laws, but denies that KVK-Tech plays a role in such independent decision. KVK-Tech further states that the statutes, articles, and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper. KVK-Tech denies all remaining allegations contained in Paragraph 153 of the FAC.

154. In response to Paragraph 154 of the FAC, KVK-Tech admits that pharmacists may, with a doctor or patient's consent, substitute a generic equivalent of a name-brand prescription medication for that of a generic prescription medication and that such actions are governed by specific laws, but denies that KVK-Tech plays a role in such independent decision. KVK-Tech denies all remaining allegations contained in Paragraph 154 of the FAC.

155. In response to Paragraph 155 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

156. In response to Paragraph 156 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

F. Generic Marketing Manufacturer Defendants Failed to Effectively Communicate with Physicians and Patients about Their Products

157. Paragraph 157 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech admits that it is a manufacturer of generic prescription opioid products, but denies any allegation expressly or impliedly asserted indicating that it did not fully comply with such duties a manufacturer has with respect to its generic prescription opioids and further denies any remaining allegations contained therein. KVK-Tech denies all remaining allegations directed against it contained therein.

158. In response to Paragraph 158 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

159. Paragraph 159 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein and states that Plaintiff's claims are preempted where it would be impossible for the Generic Manufacturers to comply with both federal law and the supposed state law duty. *See* 1:17-md-02804, Doc. Nos. 1499, pp. 34-42; 1680.

160. In response to Paragraph 160 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

161. In response to Paragraph 161 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

IV. DIVERSION DEFENDANTS HAVE LEGAL DUTIES TO PREVENT OPIOID DIVERSION

162. Paragraph 162 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech admits that it complied with any and all duties it has with respect to addressing diversion of its prescription opioid products, but denies the remaining allegations directed against it contained within Paragraph 162 of the FAC.

163. Paragraph 163 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but denies the remaining allegations directed against it contained within Paragraph 163 of the FAC.

164. Paragraph 164 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but denies the remaining allegations directed against it contained within Paragraph 164 of the FAC and states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper.

165. In response to Paragraph 165 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

A. Federal Law Sets a Standard of Care That Diversion Defendants Must Follow

1. Diversion Manufacturer Defendants' and Distributor Defendants' Standard of Care Under Federal Law

166. In response to Paragraph 166 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to

addressing diversion of its prescription opioid products, but denies the remaining allegations contained within Paragraph 166 of the FAC.

167. In response to Paragraph 167 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but denies the remaining allegations contained within Paragraph 167 of the FAC.

168. In response to Paragraph 168 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but denies the remaining allegations contained within Paragraph 168 of the FAC.

169. In response to Paragraph 169 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but denies the remaining allegations contained within Paragraph 169 of the FAC.

2. Pharmacy Defendants' Standard of Care Under Oklahoma Law

170. In response to Paragraph 170 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise

mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 170 of the FAC.

171. In response to Paragraph 171 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 171 of the FAC.

172. In response to Paragraph 172 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth,

meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 172 of the FAC.

173. In response to Paragraph 173 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 173 of the FAC.

174. In response to Paragraph 174 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 174 of the FAC.

175. In response to Paragraph 175 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that

this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 175 of the FAC.

176. In response to Paragraph 176 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 176 of the FAC.

177. In response to Paragraph 177 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth,

meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 177 of the FAC.

B. Oklahoma Law Sets a Standard of Care That Diversion Defendants Must Follow

1. Diversion Manufacturer Defendants' and Distributor Defendants' Standard of care Under Oklahoma Law

178. In response to Paragraph 178 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products and denies the allegations contained within Paragraph 178 of the FAC.

179. In response to Paragraph 179 of the FAC, the Nation's negligence per se claim has been dismissed and, therefore, no response is required. See Opinion and Order, Doc #: 1680, pp. 23-25 (*"Thus, none of the statutes cited by Plaintiffs are intended to protect Plaintiffs from the harms they allege. Plaintiffs cannot state claims for negligence per se pursuant to these statutes."*). To the extent a response is required, KVK-Tech expressly denies the same.

180. In response to Paragraph 180 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products and denies the allegations contained within Paragraph 180 of the FAC.

181. In response to Paragraph 181 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products and denies the allegations contained within Paragraph 181 of the FAC.

182. In response to Paragraph 182 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products and denies the allegations contained within Paragraph 182 of the FAC.

183. In response to Paragraph 183 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products and denies the allegations contained within Paragraph 183 of the FAC.

184. In response to Paragraph 184 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to

addressing diversion of its prescription opioid products and denies the allegations contained within Paragraph 184 of the FAC.

185. In response to Paragraph 185 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products and denies the allegations contained within Paragraph 185 of the FAC.

2. Pharmacy Defendants' Standard of Care Under Oklahoma Law

186. In response to Paragraph 186 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 186 of the FAC.

187. In response to Paragraph 187 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies

with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 187 of the FAC.

188. In response to Paragraph 188 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 188 of the FAC.

189. In response to Paragraph 189 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 189 of the FAC.

190. In response to Paragraph 190 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 190 of the FAC.

191. In response to Paragraph 191 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 191 of the FAC.

192. In response to Paragraph 192 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies

with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 192 of the FAC.

193. In response to Paragraph 193 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 193 of the FAC.

194. In response to Paragraph 194 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 194 of the FAC.

195. In response to Paragraph 195 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 195 of the FAC.

196. In response to Paragraph 196 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 196 of the FAC.

197. In response to Paragraph 197 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies

with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 197 of the FAC.

198. In response to Paragraph 198 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 198 of the FAC.

199. In response to Paragraph 199 of the FAC, KVK-Tech states that the statutory and/or other authorities cited therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “pharmacy defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge or information sufficient to form a belief as to the truth, meaning or intent of the allegations contained therein and, therefore, denies the allegations contained within Paragraph 199 of the FAC.

V. DIVERSION DEFENDANTS HAVE FAILED TO FULFILL THEIR DUTIES

A. Diversion Manufacturer Defendants and Distributor Defendants Understood Their Duties and Violated Them Anyway

1. Diversion Manufacturer Defendants and Distributor Defendants Understood and Acknowledged Their Duties

200. In response to Paragraph 200 of the FAC, KVK-Tech states that the statutory and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products and is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations and, therefore, denies the remaining allegations in Paragraph 200 of the FAC contained therein.

201. In response to Paragraph 201 of the FAC, KVK-Tech states that the articles, statutory and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products and is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations and, therefore, denies the remaining allegations in Paragraph 201 of the FAC contained therein.

202. In response to Paragraph 202 of the FAC, KVK-Tech states that the articles, statutory and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To

the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products and is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations and, therefore, denies the remaining allegations in Paragraph 202 of the FAC contained therein.

203. In response to Paragraph 203 of the FAC, KVK-Tech states that the articles, statutory and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products and is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations and, therefore, denies the remaining allegations in Paragraph 203 of the FAC contained therein.

204. In response to Paragraph 204 of the FAC, KVK-Tech states that the articles, statutory and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products and is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations and, therefore, denies the remaining allegations in Paragraph 204 of the FAC contained therein.

205. In response to Paragraph 205 of the FAC, KVK-Tech states that the articles, statutory and/or other authorities referenced therein speak for themselves and any attempt to

misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products and is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations and, therefore, denies the remaining allegations in Paragraph 205 of the FAC contained therein.

206. In response to Paragraph 206 of the FAC, KVK-Tech states that the statutory and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “distributor defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products and is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations and, therefore, denies the remaining allegations in Paragraph 206 of the FAC contained therein.

207. In response to Paragraph 207 of the FAC, KVK-Tech states that the statutory and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper. KVK-Tech further states that this allegation is not directed against it inasmuch as it is not a “distributor defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products and is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the

remaining allegations and, therefore, denies the remaining allegations in Paragraph 207 of the FAC contained therein.

208. In response to Paragraph 208 of the FAC, KVK-Tech states that this allegation is not directed against it inasmuch as it is not a “distributor defendant” and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 208 of the FAC, and therefore denies the same.

209. In response to Paragraph 209 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and that the allegations are not directed at this defendant and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 209 of the FAC, and therefore denies the same.

210. In response to Paragraph 210 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and that the allegations are not directed at this defendant and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge and information sufficient to form a belief

as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 210 of the FAC, and therefore denies the same.

211. In response to Paragraph 211 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and, no response is required. To the extent a response is required, KVK-Tech admits that it complies with any and all duties it has with respect to addressing diversion of its prescription opioid products, but is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 211 of the FAC, and therefore denies the same.

2. Prior Regulatory Actions Against Distributor Defendants for Failing to Prevent Diversion

212. In response to Paragraph 212 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and that the allegations are not directed at this defendant inasmuch as it is not a “Distributor Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 212 of the FAC, and therefore denies the same.

a. Cardinal

213. In response to Paragraph 213 of the FAC, KVK-Tech states that these allegations are not directed against it and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 213 of the FAC, and therefore denies the same.

214. In response to Paragraph 214 of the FAC, KVK-Tech states that these allegations are not directed against it and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 214 of the FAC, and therefore denies the same.

215. In response to Paragraph 215 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and KVK-Tech states that these allegations are not directed against it and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 215 of the FAC, and therefore denies the same.

216. In response to Paragraph 216 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves a KVK-Tech states that these allegations are not directed against it and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 216 of the FAC, and therefore denies the same.

217. In response to Paragraph 217 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and KVK-Tech states that these allegations are not directed against it and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it is without knowledge and information sufficient to form a belief as to the

truth, meaning, and intent of the remaining allegations contained within Paragraph 217 of the FAC, and therefore denies the same.

b. McKesson

218. In response to paragraph 218 of the FAC, KVK-Tech states that these allegations are not directed against it and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained therein and, therefore, denies the same.

219. In response to paragraph 219 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that these allegations are not directed against it and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained therein and, therefore, denies the same.

220. In response to paragraph 220 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that these allegations are not directed against it and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained therein and, therefore, denies the same.

c. AmerisourceBergen

221. In response to Paragraph 221 of the FAC, KVK-Tech states that these allegations are not directed against it and, therefore, no response is required. To the extent a response is

required, KVK-Tech states that it is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained therein and, therefore, denies the same.

222. In response to Paragraph 222 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that these allegations are not directed against it and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained therein and, therefore, denies the same.

223. In response to Paragraph 223 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that these allegations are not directed against it and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained therein and, therefore, denies the same.

3. Diversion Manufacturer Defendants Violated Their Duties in Oklahoma

224. In response to Paragraph 224 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

225. In response to Paragraph 225 of the FAC, KVK-Tech admits that it manufactures certain generic prescription opioids and states it complies with any and all duties it has with respect to addressing its prescription opioid products, but it is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations and,

therefore, denies the remaining allegations in Paragraph 225 of the FAC directed against it contained therein.

226. In response to Paragraph 226 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

227. Paragraph 227 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein and states it complies with any and all duties it has with respect to addressing its prescription opioid products.

228. In response to Paragraph 228 of the FAC, KVK-Tech denies the allegations directed against it contained therein and states it complies with any and all duties it has with respect to addressing its prescription opioid products.

229. In response to paragraph 229 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

4. Despite Prior Regulatory Actions, Distributor Defendants Violated Their Duties in Oklahoma

230. In response to Paragraph 230 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Distributor Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 230 of the FAC, and therefore denies the same.

231. In response to Paragraph 231 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Distributor Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and

information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 231 of the FAC, and therefore denies the same.

232. In response to Paragraph 232 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Distributor Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 232 of the FAC, and therefore denies the same.

233. In response to Paragraph 233 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Distributor Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 233 of the FAC, and therefore denies the same.

234. In response to Paragraph 234 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Distributor Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 234 of the FAC, and therefore denies the same.

235. In response to Paragraph 235 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Distributor Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 235 of the FAC, and therefore denies the same.

236. In response to Paragraph 236 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Distributor Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 236 of the FAC, and therefore denies the same.

B. Pharmacy Defendants Understood Their Duties and Violated Them Anyway

1. Pharmacy Defendants Understood and Acknowledged Their Duties

237. In response to Paragraph 237 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 237 of the FAC, and therefore denies the same.

238. In response to Paragraph 238 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 238 of the FAC, and therefore denies the same.

239. In response to Paragraph 239 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is

required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 239 of the FAC, and therefore denies the same.

240. In response to Paragraph 240 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 240 of the FAC, and therefore denies the same.

241. In response to Paragraph 241 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 241 of the FAC, and therefore denies the same.

242. In response to Paragraph 242 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 242 of the FAC, and therefore denies the same.

243. In response to Paragraph 243 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 243 of the FAC, and therefore denies the same.

244. In response to Paragraph 244 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 244 of the FAC, and therefore denies the same.

2. Prior Regulatory Actions Against Pharmacy Defendants for Failing to Prevent Diversion

245. In response to Paragraph 245 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 245 of the FAC, and therefore denies the same.

246. In response to Paragraph 246 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and

information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 246 of the FAC, and therefore denies the same.

a. CVS

247. In response to Paragraph 247 of the FAC, KVK-Tech states that the allegations are not directed at this defendant, and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 247 of the FAC, and therefore denies the same.

248. In response to Paragraph 248 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant, and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 248 of the FAC, and therefore denies the same.

249. In response to Paragraph 249 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant, and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 249 of the FAC, and therefore denies the same.

250. In response to Paragraph 250 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant, and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 250 of the FAC, and therefore denies the same.

251. In response to Paragraph 251 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant, and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 251 of the FAC, and therefore denies the same.

252. In response to Paragraph 252 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant, and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 252 of the FAC, and therefore denies the same.

b. Walgreens

253. In response to Paragraph 253 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant, and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 253 of the FAC, and therefore denies the same.

254. In response to Paragraph 254 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant, and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 254 of the FAC, and therefore denies the same.

255. In response to Paragraph 255 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant, and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 255 of the FAC, and therefore denies the same.

c. Walmart

256. In response to Paragraph 256 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that the allegations are not directed at this defendant, and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 256 of the FAC, and therefore denies the same.

3. Despite Prior Regulatory Actions, Pharmacy Defendants Continue to Violate Their Duties

257. In response to Paragraph 257 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 257 of the FAC, and therefore denies the same.

258. In response to Paragraph 258 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 258 of the FAC, and therefore denies the same.

259. In response to Paragraph 259 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and

information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 259 of the FAC, and therefore denies the same.

260. In response to Paragraph 260 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 260 of the FAC, and therefore denies the same.

261. In response to Paragraph 261 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 261 of the FAC, and therefore denies the same.

262. In response to Paragraph 262 of the FAC, KVK-Tech states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 262 of the FAC, and therefore denies the same.

VI. DEFENDANTS’ MISCONDUCT HAS INJURED AND CONTINUES TO INJURE THE NATION AND ITS CITIZENS

263. Paragraph 263 of the FAC calls for legal conclusions to which no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein.

A. Marketing Manufacturer Defendants’ Misconduct Has Injured and Continues to Injure the Nation and Its Citizens

264. In response to Paragraph 264 of the FAC, KVK-Tech states that the statistics, studies, articles, and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

265. In response to Paragraph 265 of the FAC, KVK-Tech states that the statistics, studies, articles, and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

266. In response to Paragraph 266 of the FAC, KVK-Tech states that the statistics, studies, articles, and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

267. In response to Paragraph 267 of the FAC, KVK-Tech states that the statistics, studies, articles, and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

268. In response to Paragraph 268 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

269. In response to Paragraph 269 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

270. In response to Paragraph 270 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

271. In response to Paragraph 271 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

272. In response to Paragraph 272 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

273. In response to Paragraph 273 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

B. Diversion Manufacturer Defendants' and Distributor Defendants' Misconduct Has Injured and Continues to Injure the Nation and Its Citizens

274. Paragraph 274 of the FAC calls for legal conclusions to which no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein.

275. Paragraph 275 of the FAC calls for legal conclusions to which no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein.

276. In response to Paragraph 276 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

277. In response to Paragraph 277 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

278. In response to Paragraph 278 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

279. In response to Paragraph 279 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

280. In response to Paragraph 280 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

281. In response to Paragraph 281 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

282. In response to Paragraph 282 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

283. In response to Paragraph 283 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

284. In response to Paragraph 284 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

C. Pharmacy Defendants' Misconduct Has Injured and Continues to Injure the Nation and Its Citizens

285. In response to Paragraph 285 of the FAC, states that the allegations are not directed at this defendant inasmuch as it is not a "Pharmacy Defendant," and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 285 of the FAC, and therefore denies the same.

286. In response to Paragraph 286 of the FAC, states that the allegations are not directed at this defendant inasmuch as it is not a "Pharmacy Defendant," and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 286 of the FAC, and therefore denies the same.

287. In response to Paragraph 287 of the FAC, states that the allegations are not directed at this defendant inasmuch as it is not a "Pharmacy Defendant," and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information

sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 287 of the FAC, and therefore denies the same.

288. In response to Paragraph 288 of the FAC, states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 288 of the FAC, and therefore denies the same.

289. In response to Paragraph 289 of the FAC, states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 289 of the FAC, and therefore denies the same.

290. In response to Paragraph 290 of the FAC, states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 290 of the FAC, and therefore denies the same.

291. In response to Paragraph 291 of the FAC, states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 291 of the FAC, and therefore denies the same.

292. In response to Paragraph 292 of the FAC, states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 292 of the FAC, and therefore denies the same.

293. In response to Paragraph 293 of the FAC, states that the allegations are not directed at this defendant inasmuch as it is not a “Pharmacy Defendant,” and, therefore, no response is required. To the extent a response is required, KVK-Tech is without knowledge and information sufficient to form a belief as to the truth, meaning, and intent of the remaining allegations contained within Paragraph 293 of the FAC, and therefore denies the same.

D. Defendants’ Misconduct Has Damaged the Nation and Its Citizens

294. In response to Paragraph 294 of the FAC, KVK-Tech denies the allegations directed against it and further denies the damages claimed by the Nation contained therein.

VII. FACTS PERTAINING TO CLAIMS UNDER RICO

295. In response to Paragraph 295 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

A. The Opioid Marketing Enterprise

1. The Common Purpose and Scheme of the Opioid Marketing Enterprise

296. In response to Paragraph 296 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

297. In response to Paragraph 297 of the FAC, KVK-Tech states that the studies, articles and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or

otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

298. In response to Paragraph 298 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

299. In response to Paragraph 299 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

300. In response to Paragraph 300 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

301. In response to Paragraph 301 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

302. In response to Paragraph 302 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

303. In response to Paragraph 303 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

2. The Conduct of the Opioid Marketing Enterprise

304. In response to Paragraph 304 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

305. In response to Paragraph 305 of the FAC, KVK-Tech states that the studies, articles, statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

306. In response to Paragraph 306 of the FAC, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or

otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

307. In response to Paragraph 307 of the FAC, KVK-Tech states that the studies, articles, statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

308. In response to Paragraph 308 of the FAC, KVK-Tech states that the studies, articles, statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

309. In response to Paragraph 309 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

310. In response to Paragraph 310 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

311. In response to Paragraph 311, including all subparagraphs a-l, of the FAC, KVK-Tech denies the allegations directed against it contained therein.

312. In response to Paragraph 312 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

313. In response to Paragraph 313, including all subparagraphs a-f, of the FAC, KVK-Tech states that the studies, articles, statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

314. In response to Paragraph 314, including all subparagraphs a-f, of the FAC, KVK-Tech states that the studies, articles, statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

315. In response to Paragraph 315 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

316. In response to Paragraph 316 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

317. In response to Paragraph 317 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

318. In response to Paragraph 318 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

3. The Pattern of Racketeering Activity

319. In response to Paragraph 319 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

320. In response to Paragraph 320 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

321. In response to Paragraph 321 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

322. In response to Paragraph 322 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

323. In response to Paragraph 323 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

324. In response to Paragraph 324, including all subparagraphs a-i, of the FAC, KVK-Tech denies the allegations directed against it contained therein.

325. In response to Paragraph 325 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

326. In response to Paragraph 326 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

327. In response to Paragraph 327 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

328. In response to Paragraph 328 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

B. The Opioid Supply Chain Enterprise

1. The Common Purpose and Scheme of the Opioid Supply Chain Enterprise

329. In response to Paragraph 329 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

330. In response to Paragraph 330 of the FAC, KVK-Tech states that the studies, articles, statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

331. Paragraph 331 of the FAC calls for legal conclusions to which no response is required. To the extent a response is required, KVK-Tech states that the statements and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and states that it satisfied and complied with all legal duties

it had with respect to its generic prescription opioids and denies the allegations directed against it contained therein.

332. In response to Paragraph 332 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

2. The Conduct of the Opioid Supply Chain Enterprise

333. In response to Paragraph 333 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

334. In response to Paragraph 334, including all subparagraphs a-b, of the FAC, KVK-Tech denies the allegations directed against it contained therein.

335. Paragraph 335 calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that it satisfied and complied with all legal duties it had with respect to its generic prescription opioids and denies the allegations directed against it contained therein.

336. In response to Paragraph 336 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

3. The Pattern of Racketeering Activity

337. In response to Paragraph 337 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

338. In response to Paragraph 338 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

339. In response to Paragraph 339 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

340. In response to Paragraph 340, including all subparagraphs a-n, of the FAC, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

341. In response to Paragraph 341 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

342. In response to Paragraph 342 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

343. In response to Paragraph 343 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

344. In response to Paragraph 344 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

345. In response to Paragraph 345 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

346. In response to Paragraph 346 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

347. In response to Paragraph 347 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

348. In response to Paragraph 348 of the FAC, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

349. In response to Paragraph 349 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

C. Effects of the Opioid Marketing Enterprise and the Opioid Supply Chain Enterprise

350. In response to Paragraph 350 of the FAC calls for legal conclusions to which no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein.

351. In response to Paragraph 351 of the FAC calls for legal conclusions to which no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein.

352. Paragraph 352 of the FAC calls for legal conclusions to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

CLAIMS FOR RELIEF

COUNT I

**VIOLATION OF RICO, 18 U.S.C. § 1961 *et seq.*
OPIOID MARKETING ENTERPRISE
(Against the Marketing Manufacturer Defendants)**

353. In response to Paragraph 353 of the FAC, the KVK-Tech incorporates by references all of its objections, preliminary statements, answers asserted above to Paragraphs 1-352, and its affirmative defenses as if full set forth herein.

354. Paragraph 354 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other

authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

355. Paragraph 355 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

356. In response to Paragraph 356 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

357. In response to Paragraph 357 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

358. In response to Paragraph 358 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

359. In response to Paragraph 359 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

360. In response to Paragraph 360 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

361. In response to Paragraph 361 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

362. In response to Paragraph 362 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

363. In response to Paragraph 363 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

364. Paragraph 364 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

365. In response to Paragraph 365 of the FAC, KVK-Tech denies the allegations contained therein.

366. In response to Paragraph 366 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

367. Paragraph 367, including all subparagraphs a-b, of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

368. In response to Paragraph 368 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

369. In response to Paragraph 369 of the FAC, KVK-Tech denies the allegations directed against it contained therein

370. In response to Paragraph 370 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

371. Paragraph 371 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

372. In response to Paragraph 372 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

373. In response to Paragraph 373 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

374. In response to Paragraph 374 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

375. In response to Paragraph 375 of the FAC, KVK-Tech d denies the allegations directed against it contained therein.

376. In response to Paragraph 376 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

377. In response to Paragraph 377 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

378. In response to Paragraph 378 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

379. In response to Paragraph 379 of the FAC, KVK-Tech denies the allegations directed against it and denies the damages claimed by the Nation contained therein.

COUNT II

**VIOLATION OF RICO, 18 U.S.C. § 1961 *et seq.*
OPIOID SUPPLY CHAIN ENTERPRISE
(Against All Defendants)**

380. In response to Paragraph 380 of the FAC, the KVK-Tech incorporates by references all of its objections, preliminary statements, answers asserted above to Paragraphs 1-379, and its affirmative defenses as if full set forth herein.

381. Paragraph 381 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

382. Paragraph 382 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

383. In response to Paragraph 383 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

384. In response to Paragraph 384 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

385. Paragraph 385 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise

mischaracterize the same is improper and denies the allegations directed against it contained therein.

386. Paragraph 386 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

387. Paragraph 387 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

388. Paragraph 388 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

389. Paragraph 389 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

390. In response to Paragraph 390 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

391. In response to Paragraph 391 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

392. Paragraph 392, including all subparagraphs a-d, of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

393. In response to Paragraph 393 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

394. In response to Paragraph 394 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

395. In response to Paragraph 395 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

396. In response to Paragraph 396 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

397. In response to Paragraph 397 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

398. In response to Paragraph 398 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

399. In response to Paragraph 399 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

400. In response to Paragraph 400 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

401. In response to Paragraph 401 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

402. Paragraph 402 of the FAC calls for a legal conclusion to which no response is required. To the extent a response is required, KVK-Tech states that the statutes and/or other authorities referenced therein speak for themselves and any attempt to misstate and/or otherwise mischaracterize the same is improper and denies the allegations directed against it contained therein.

403. In response to Paragraph 403 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

404. In response to Paragraph 404 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

405. In response to Paragraph 405 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

406. In response to Paragraph 406 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

407. In response to Paragraph 407 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

408. In response to Paragraph 408 of the FAC, KVK-Tech denies the allegations directed against it and denies the damages claimed by the Nation contained therein.

COUNT III

**LANHAM ACT
(Against All Defendants)**

409. In response to Paragraph 409 of the FAC, KVK-Tech incorporates by reference all of its objections, preliminary statements, answers asserted above to Paragraphs 1-408, and its affirmative defenses as if full set forth herein. However, no response is required to this Count inasmuch as it is no longer a viable cause of action inasmuch as the Court has dismissed the claim with prejudice. *See* 1:17-md-02804, Doc. Nos. 1499, pp. 47-50 (“*Plaintiff is not a proper plaintiff under the Lanham Act because it has not alleged an ‘injury to a commercial interest in reputation or sales’ as required to have standing.*”); *See also* Doc. No. 1680. To the extent a response is required, KVK-Tech denies all allegations asserted against it herein and below.

410. In response to Paragraph 410 of the FAC, the Nation’s claim under the Lanham Act has been dismissed with prejudice by this Court and, therefore, no response is required. *See* 1:17-md-02804, Doc. Nos. 1499, pp. 47-50; *See also* Doc. No. 1680.

411. In response to Paragraph 411 of the FAC, the Nation’s claim under the Lanham Act has been dismissed with prejudice by this Court and, therefore, no response is required. *Id.*

412. In response to Paragraph 412 of the FAC, the Nation’s claim under the Lanham Act has been dismissed with prejudice by this Court and, therefore, no response is required. *Id.*

413. In response to Paragraph 413 of the FAC, the Nation’s claim under the Lanham Act has been dismissed with prejudice by this Court and, therefore, no response is required. *Id.*

414. In response to Paragraph 414 of the FAC, the Nation’s claim under the Lanham Act has been dismissed with prejudice by this Court and, therefore, no response is required. *Id.*

415. In response to Paragraph 415 of the FAC, the Nation’s claim under the Lanham Act has been dismissed with prejudice by this Court and, therefore, no response is required. *Id.*

416. In response to Paragraph 416 of the FAC, the Nation's claim under the Lanham Act has been dismissed with prejudice by this Court and, therefore, no response is required. *Id.*

417. In response to Paragraph 417 of the FAC, the Nation's claim under the Lanham Act has been dismissed with prejudice by this Court and, therefore, no response is required. *Id.*

418. In response to Paragraph 418 of the FAC, the Nation's claim under the Lanham Act has been dismissed with prejudice by this Court and, therefore, no response is required. *Id.*

COUNT IV

NUISANCE

(Against Marketing Manufacturer Defendants)

419. In response to Paragraph 419 of the FAC, the KVK-Tech incorporates by references all of its objections, preliminary statements, answers asserted above to Paragraphs 1-418, and its affirmative defenses as if full set forth herein.

420. In response to Paragraph 420 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

421. In response to Paragraph 421, including all subparagraphs a-f, of the FAC, KVK-Tech denies the allegations directed against it contained therein.

422. In response to Paragraph 422, including all subparagraphs a-e, of the FAC, KVK-Tech denies the allegations directed against it contained therein.

423. In response to Paragraph 423 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

424. In response to Paragraph 424 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

425. In response to Paragraph 425 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

426. In response to Paragraph 426 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

427. In response to Paragraph 427 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

428. In response to Paragraph 428 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

429. In response to Paragraph 429 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

430. In response to Paragraph 430 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

431. In response to Paragraph 431 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

432. In response to Paragraph 432 of the FAC, KVK-Tech denies the allegations directed against it and denies the damages claimed by the Nation contained therein.

COUNT V

NEGLIGENCE AND NEGLIGENCE PER SE (Against Marketing Manufacturer Defendants)

433. In response to Paragraph 433 of the FAC, the KVK-Tech incorporates by references all of its objections, preliminary statements, answers asserted above to Paragraphs 1-432, and its affirmative defenses as if full set forth herein. In addition, KVK-Tech further states that this Court has dismissed the Nation's Negligence Per Se claims with prejudice (*See* MDL 1:17-md-02804-DAP, Doc. No.: 1680, pp. 23-25 (“*Thus, none of the statutes cited by Plaintiffs are intended to protect Plaintiffs from the harms they allege. Plaintiffs cannot state claims for negligence per se pursuant to these statutes.*”), and, therefore, any allegations concerning a claim for negligence per

se are not only expressly denied, but must be disregarded; thus, the following answers are only directed towards the Nation's claim for Negligence contained within Count V.

434. Paragraph 434 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

435. Paragraph 435 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

436. Paragraph 436, including all subparagraphs a-f, of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

437. Paragraph 437 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

438. In response to Paragraph 438 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

439. Paragraph 439 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

440. Paragraph 440 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

441. Paragraph 441 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

442. Paragraph 442 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein. KVK-Tech further states that this Court has dismissed the Nation's Negligence Per Se claims (*See* MDL 1:17-md-

02804-DAP, Doc No.: 1680, pp. 23-25), and, therefore, any allegations concerning a claim for negligence per se are not only expressly denied, but must be disregarded.

443. Paragraph 443 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein. KVK-Tech further states that this Court has dismissed the Nation's Negligence Per Se claims (*See* MDL 1:17-md-02804-DAP, Doc. No.: 1680, pp. 23-25), and, therefore, any allegations concerning a claim for negligence per se are not only expressly denied, but must be disregarded.

444. In response to Paragraph 444 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

445. In response to Paragraph 445 of the FAC, KVK-Tech denies the allegations directed against it and denies the damages claimed by the Nation contained therein.

COUNT VI

UNJUST ENRICHMENT (Against Marketing Manufacturer Defendants)

446. In response to Paragraph 446 of the FAC, the KVK-Tech incorporates by references all of its objections, preliminary statements, answers asserted above to Paragraphs 1-445, and its affirmative defenses as if full set forth herein.

447. In response to Paragraph 447 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

448. In response to Paragraph 448 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

449. In response to Paragraph 449 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

450. In response to Paragraph 450 of the FAC, KVK-Tech denies the allegations directed against it and denies the damages claimed by the Nation contained therein.

COUNT VII

NUISANCE

(Against Diversion Defendants)

451. In response to Paragraph 451 of the FAC, the KVK-Tech incorporates by references all of its objections, preliminary statements, answers asserted above to Paragraphs 1-450, and its affirmative defenses as if full set forth herein.

452. In response to Paragraph 452, including all subparagraphs a-d, of the FAC, KVK-Tech denies the allegations directed against it contained therein.

453. In response to Paragraph 453, including all subparagraphs a-f, of the FAC, KVK-Tech denies the allegations directed against it contained therein.

454. In response to Paragraph 454, including all subparagraphs a-e, of the FAC, KVK-Tech denies the allegations directed against it contained therein.

455. Paragraph 455 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

456. Paragraph 456 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise

denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

457. In response to Paragraph 457 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

458. In response to Paragraph 458 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

459. Paragraph 459 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

460. In response to Paragraph 460 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

461. In response to Paragraph 461 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

462. In response to Paragraph 462 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

463. Paragraph 463 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

464. Paragraph 464 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations and denies the damages claimed by the Nation contained therein.

COUNT VIII

NEGLIGENCE AND NEGLIGENCE PER SE (Against Diversion Defendants)

465. In response to Paragraph 465 of the FAC, the KVK-Tech incorporates by references all of its objections, preliminary statements, answers asserted above to Paragraphs 1-464, and its affirmative defenses as if full set forth herein. In addition, KVK-Tech further states that this Court has dismissed the Nation's Negligence Per Se claims (*See MDL 1:17-md-02804-DAP, Doc No.: 1680, pp. 23-25 ("Thus, none of the statutes cited by Plaintiffs are intended to protect Plaintiffs from the harms they allege. Plaintiffs cannot state claims for negligence per se pursuant to these statutes.")*), with prejudice, and, therefore, any allegations concerning a claim for negligence per se are not only expressly denied, but must be disregarded; thus, the following answers are only directed towards the Nation's claim for Negligence contained in Count VIII.

466. Paragraph 466 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

467. Paragraph 467 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

468. Paragraph 468, including all subparagraphs a-j, of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

469. Paragraph 469 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

470. Paragraph 470 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech admits that it manufactured certain generic prescription opioid products and admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

471. Paragraph 471 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein.

472. Paragraph 472 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein.

473. Paragraph 473 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

474. Paragraph 474 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

475. Paragraph 475 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein. In addition, KVK-Tech further states that this Court has dismissed the Nation's Negligence Per Se claims with prejudice

(See MDL 1:17-md-02804-DAP, Doc #: 1680, pp. 23-25), and, therefore, any allegations concerning a claim for negligence per se are not only expressly denied, but must be disregarded.

476. Paragraph 476 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech states that it admits that it satisfied and/or complied with all legal duties regarding its prescription opioid products and otherwise denies the allegations directed against it inconsistent with what KVK-Tech has admitted contained therein and otherwise denies any remaining allegations contained therein.

477. Paragraph 477 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it contained therein.

478. Paragraph 478 of the FAC calls for a legal conclusion and, therefore, no response is required. To the extent a response is required, KVK-Tech denies the allegations directed against it and denies the damages claimed by the Nation contained therein.

COUNT IX

UNJUST ENRICHMENT (Against Diversion Defendants)

479. In response to Paragraph 479 of the FAC, the KVK-Tech incorporates by references all of its objections, preliminary statements, answers asserted above to Paragraphs 1-478, and its affirmative defenses as if full set forth herein.

480. In response to Paragraph 480 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

481. In response to Paragraph 481 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

482. In response to Paragraph 482 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

483. In response to Paragraph 483 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

484. In response to Paragraph 484 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

COUNT X

CIVIL CONSPIRACY (Against All Defendants)

485. In response to Paragraph 485 of the FAC, the KVK-Tech incorporates by references all of its objections, preliminary statements, answers asserted above to Paragraphs 1-484, and its affirmative defenses as if full set forth herein.

486. In response to Paragraph 486 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

487. In response to Paragraph 487 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

488. In response to Paragraph 488 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

489. In response to Paragraph 489 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

490. In response to Paragraph 490 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

491. In response to Paragraph 491 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

492. In response to Paragraph 492 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

493. In response to Paragraph 493 of the FAC, KVK-Tech denies the allegations directed against it contained therein.

PRAYER FOR RELIEF

KVK-Tech expressly denies that Plaintiff The Muscogee (Creek) Nation is entitled to any of the requested prayer for relief in Plaintiff's First Amended Complaint.

REQUEST FOR JURY TRIAL

KVK-Tech makes no response to this section inasmuch as it states conclusions of law and/or is not an allegation contemplated by the Federal or Oklahoma Rules of Civil Procedure.

WHEREFORE, Defendant KVK-Tech, Inc. respectfully request that judgment be entered in its favor and against the Plaintiff The Muscogee (Creek) Nation on all claims and further requests that it be awarded costs and attorneys' fees and such other further relief that the Court deems appropriate and just.

AFFIRMATIVE AND ADDITIONAL DEFENSES

Defendant KVK-Tech, Inc. ("KVK-Tech") hereby asserts the following affirmative and additional defenses to the allegations and claims in Plaintiff's First Amended Complaint ("FAC"). By asserting the matters now, KVK-Tech does not admit that the Plaintiff is relieved of its burden to prove each element of its claims and the damage or relief sought.

FIRST AFFIRMATIVE AND ADDITIONAL DEFENSE

1. The Plaintiff's claims are barred because the FAC fails to state a claim upon which relief can be granted, fails to state facts sufficient to constitute a cause of action, and fails to plead a legally cognizable injury.

SECOND AFFIRMATIVE AND ADDITIONAL DEFENSE

2. The Plaintiff's claims are barred, in whole or in part, by the applicable statute(s) of limitations and/or statute(s) of repose, including, but not limited to, 12 Okla. Stat. § 95(A) and 63 Okla. Stat. § 5053.6. Under Oklahoma law, a cause of action accrues when the Plaintiff knew or reasonably should have known of a wrongfully caused injury to itself or to its Members. Here, the Plaintiff alleges wrongfully caused injuries that occurred over an unspecified period of time. *See generally* First Amended Complaint. The Plaintiff and/or its Members would have known of, or reasonably should have known of, at least some of these purported injuries outside of the relevant limitations period. To the extent that the Plaintiff knew or should have known of any wrongfully caused injuries outside the applicable limitations period, Plaintiffs claims are time-barred.

THIRD AFFIRMATIVE AND ADDITIONAL DEFENSE

3. The Plaintiff's claims are barred by the doctrine of primary jurisdiction. The Plaintiff's allegations implicate medical and scientific issues that are outside the conventional experience of judges and particularly within the FDA's expertise, discretion, and regulatory authority.

FOURTH AFFIRMATIVE AND ADDITIONAL DEFENSE

4. The rights of KVK-Tech under the Due Process Clause of the U.S. Constitution and Art. II, § 7 of the Oklahoma Constitution are violated by any financial or other arrangement that might distort the Nation's Attorney General's duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding. *See, e.g., Marshall v. Jerrico, Inc.*, 446 U.S. 238 (1980). Any contingency fee arrangement between the Plaintiff and any third party in connection with this litigation gives that third party a financial interest in the outcome of this proceeding and violates the due process rights of KVK-Tech.

FIFTH AFFIRMATIVE AND ADDITIONAL DEFENSE

5. The Plaintiff has failed to join one or more necessary and indispensable parties, including without limitation governmental agencies, commissions, departments, subdivisions or entities claiming entitlement to relief arising from or related to the allegations of the FAC and health care providers, prescribers, patients, and other third parties whom the Plaintiff alleges engaged in the unauthorized or illicit prescription, dispensing, diversion, or use of prescription opioid products in Oklahoma. *See generally* First Amended Complaint. These third parties have a legal interest in the subject matter of the litigation to the extent they assert a right or claim to relief or to the extent they facilitated and/or participated in the opioid misuse, abuse, and related misconduct alleged in the FAC. The Plaintiff has failed to name any such third parties as plaintiffs or as defendants respectively, nor has the Plaintiff alleged how, if at all, it would be infeasible to join one or more indispensable but absent parties.

SIXTH AFFIRMATIVE AND ADDITIONAL DEFENSE

6. The Plaintiff's claims are barred because they are preempted by federal law, including without limitation the federal Controlled Substances Act and the Food, Drug, and Cosmetic Act ("FDCA"). To the extent the Plaintiff's claims seek to hold KVK-Tech liable for promoting opioid products for their FDA-approved uses, the claims are preempted. Granting such relief would impede, impair, frustrate, or burden the effectiveness of federal law and would violate the Supremacy Clause of the United States Constitution. Indeed, Plaintiff's claims are preempted insofar as they conflict with Congress' purposes and objectives in enacting relevant federal legislation and authorizing regulations, including the Hatch-Waxman Amendments to the FDCA and implementing regulations. *See Geier v. Am. Honda Co.*, 529 U.S. 861 (2000). To the extent the Plaintiff's claims are inconsistent with the determinations of FDA based on the information

provided to FDA, or otherwise assert that incorrect, incomplete or inaccurate information was provided to the FDA, the claims are also preempted. *See, e.g., Buckman v. Pls.' Legal Comm.*, 531 U.S. 341 (2001); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34 (1st Cir. 2015); *Yates v. OrthoMcNeil-Janssen Pharms., Inc.*, 808 F.3d 281 (6th Cir. 2015).

SEVENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

7. The Plaintiff's claims are barred by the doctrines of laches, waiver, equitable estoppel, and/or unclean hands. The Plaintiff complains of injuries and conduct that predate the commencement of this action by decades. The Plaintiff admits that at the time it commenced the instant action, it was continuing to reimburse opioid prescriptions written for indications that the Plaintiff now contends are not medically necessary, reasonably required, and/or dispensed for an FDA-approved purpose, precluding the Plaintiff from claiming it was misled by KVK-Tech's alleged misconduct. Upon information and belief, the Plaintiff did not reject, disapprove, or object to claims for reimbursement of KVK-Tech's opioids for off-label indications before it filed its FAC. The Plaintiff's claims against KVK-Tech thus are barred by the doctrines of waiver and/or estoppel. The Plaintiff's failure to exercise diligence in bringing this action has prejudiced KVK-Tech by depriving it the opportunity to alter its allegedly improper practices, if necessary. As a matter of equity, therefore, the doctrine of laches should bar the Plaintiff from recovering on its claims. Further, the inequitable conduct of the Plaintiff alleged above precludes the Plaintiff from entitlement to any equitable remedies under the doctrine of unclean hands.

EIGHTH AFFIRMATIVE AND ADDITIONAL DEFENSE

8. With respect to the Plaintiff's claim for unjust enrichment, and to the extent the Plaintiff seeks any additional equitable relief, such relief is unavailable to the extent the Plaintiff is also deemed to have an adequate remedy at law.

NINTH AFFIRMATIVE AND ADDITIONAL DEFENSE

9. The Plaintiff's claims are barred by the learned intermediary doctrine. At all relevant times herein, the physicians and other health care providers who prescribed KVK-Tech's opioid products at issue were in the position of learned intermediaries, who are presumed to have knowledge of a drug label's contents and who used their informed, independent medical judgment in making their prescribing and treatment decisions for a given patient. These prescribers had many sources of information about those products available to them, including the products' FDA-approved labeling, which informed prescribers of the risks and benefits of KVK-Tech's products, and these prescribers relied on a variety of factors separate from and unrelated to KVK-Tech's alleged misrepresentations in making their prescribing decisions. *See generally* First Amended Complaint. Regardless of the learned intermediary doctrine's origination in product liability law, its principles still establish a superseding interruption in the necessary chain of causation between any alleged conduct by KVK-Tech and the Plaintiff's alleged injuries, and/or preclude the Plaintiff from establishing that physicians and other health care providers reasonably relied on any alleged misrepresentations by KVK-Tech inconsistent with the providers' informed and independent medical judgment and/or relied to their detriment upon any statement by KVK-Tech, in determining to use or prescribe the subject prescription medication(s).

TENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

10. The Plaintiff's claims against KVK-Tech and other Defendants do not arise out of the same transaction, occurrence, or series of transactions or occurrences as required by 12 Okla. Stat. § 2020 and/or Fed. R. Civ. P. 20 for joinder of parties. Plaintiff fails to connect any of the alleged marketing activities of KVK-Tech to those of other Defendants, nor could it. Accordingly,

the Court should sever or dismiss the Plaintiff's claims against KVK-Tech pursuant to 12 Okla. Stat. §§ 2020 and 2021 and/or Fed. R. Civ. P. 20 and 21.

ELEVENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

11. The Plaintiff's alleged loss, damage, injury, harm, expense, diminution, or deprivation, if any, was caused in whole or in part by the Plaintiff's ratification of KVK-Tech's or other Defendants' allegedly deceptive or misleading conduct. Such ratification would include, for example, the Plaintiff's continuing reimbursement of opioid prescriptions after it had concluded such prescriptions were ineffective or harmful to its Members, medically unnecessary, or otherwise ineligible for payment by the Plaintiff. In addition and/or in the alternative, Plaintiff fails to plead and cannot establish that it incurred any costs for any opioid prescription promoted or sold by KVK-Tech and that was medically inappropriate or should not have been written, or that KVK-Tech's allegedly improper conduct caused any health care provider to write any unnecessary, ineffective or harmful opioid prescriptions.

TWELFTH AFFIRMATIVE AND ADDITIONAL DEFENSE

12. The Plaintiff's claims against KVK-Tech are barred to the extent that any rely on or implicate the negligent, intentional, malicious, criminal, and/or otherwise unlawful acts or omissions of the Plaintiff or third parties that are not subject to KVK-Tech's control or authority and for which KVK-Tech is not responsible and cannot be held liable. These include but are not limited, to health care providers, prescribers, patients, and other third parties whom the Plaintiff alleges engaged in the unauthorized, illicit, or unlawful distribution, prescription, dispensing, diversion, use, misuse, or abuse of prescription opioid products in Oklahoma and to Plaintiff's Members. KVK-Tech's liability, if any, therefore must be reduced or negated to the extent that third parties have contributed to, or caused, the Plaintiff's injuries.

THIRTEENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

13. To the extent the Plaintiff's claims are based the alleged conduct of other Defendants, and the Plaintiff seeks to impose liability on KVK-Tech only by virtue of KVK-Tech's ownership of another Defendant's shares, membership within another Defendant's unincorporated entity, or similar affiliation, the Plaintiff has failed to plead allegations sufficient to support a claim to pierce the corporate veil, or to otherwise hold KVK-Tech liable merely by virtue of its corporate affiliation with other Defendants.

FOURTEENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

14. The Plaintiff's claims are barred by, in whole or in part, the applicable provisions of the United States Constitution and the Oklahoma Constitution, including but not limited to the First Amendment to the United States Constitution and/or Article II, Section 22 of the Oklahoma Constitution, and/or that of any other state whose laws may apply. The Plaintiff's claims rely on allegations that KVK-Tech engaged in various marketing activities relating to opioid products, including advertisements, detailing, speaker programs, and other promotional efforts. These activities concern lawful activity, are neither false nor misleading, and thus constitute constitutionally protected commercial speech, including, but not limited to, under the *Noerr-Pennington* doctrine, the Constitution of the State of Oklahoma, Ohio, and/or any other state whose laws may apply, such claims are barred.

FIFTEENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

15. The Plaintiff's claims, or at a minimum, its requests for relief are barred because KVK-Tech's alleged misrepresentations, or any other allegedly injurious conduct, were not the proximate or legal cause of the purported injuries or damages incurred by the Plaintiff or any other party. The physicians and other health care Professionals who prescribed KVK-Tech's opioid

product(s) at issue as alleged in the FAC had many sources of information about those products available to them, including the products' FDA-approved labeling, which informed physicians of the risks and benefits of these products, and these prescribers relied on a variety of factors separate from KVK-Tech's alleged misrepresentations in making their prescribing decisions, if they relied upon KVK-Tech's alleged marketing at all. Furthermore, prescriber decisions were also affected by other independent superseding causes and/or intervening events, which were not reasonably foreseeable and not caused by KVK-Tech and for which KVK-Tech is not liable, that broke any causal chain, including individual patients' preferences, patients' decision to fill a prescription, patients' decision whether and how to use the medication, and the Plaintiff's decision whether and when to cover the drug for the particular indication and reimburse for the particular prescription. As a consequence, the alleged injuries asserted by the Plaintiff are too remote from the alleged conduct or omissions of KVK-Tech to be a basis for liability as a matter of law and due process. See U.S. Const. Amend. V.

SIXTEENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

16. The Plaintiff's claims are barred to the extent providers prescribed and/or their patients used Plaintiff's products after becoming aware of and/or learning of their alleged risks. Further, the Plaintiff's claims are barred to the extent the Plaintiff reimbursed opioid prescription claims, or incurred any other form of alleged damages, after becoming aware of the alleged risks associated with KVK-Tech's products. In addition and/or in the alternative, any recovery by Plaintiff may be barred or limited by the principles of informed consent, whether primary, express, or implied.

SEVENTEENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

17. The Plaintiff's claims are barred, in whole or in part, by the doctrines of contributory or comparative negligence, and/or contributory or comparative fault, for reasons including, but not limited to Plaintiff's alleged injuries and/or damages were caused, in whole or in part, by its own failure to effectively enforce the law and prosecute violations thereof and any recovery by Plaintiff is barred or, alternatively, should be diminished according to its own fault, as recognized and applicable under 23 Okla. Stat. §§ 13, 14 and/or that of any other state whose laws may apply.

EIGHTEENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

18. The Plaintiff's claims are barred or limited by the Plaintiff's failure to mitigate its alleged damages. To the extent the Plaintiff mitigated, minimized, or avoided damages allegedly sustained or unreasonably failed to mitigate, minimize, or avoid any damages, any economic damages attributable to the alleged conduct of KVK-Tech must be reduced by that amount.

NINETEENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

19. To the extent any agents, employees, or contractors of KVK-Tech caused any of the damages alleged by the Plaintiff, such agents, employees, or contractors were acting outside the scope of the agency, employment, or contract with KVK-Tech, and any recovery against KVK-Tech must be reduced by the proportionate fault of such agents, employees, or contractors.

TWENTIETH AFFIRMATIVE AND ADDITIONAL DEFENSE

20. Any damage or injury to the Plaintiff must be set off against the benefits to the Plaintiff as a result of KVK-Tech's lawful activity. Further, in the event KVK-Tech is held liable to the Plaintiff, KVK-Tech would be entitled to a set-off for all sums of money received or available from or on behalf of any other parties liable for the same alleged injury.

TWENTY-FIRST AFFIRMATIVE AND ADDITIONAL DEFENSE

21. The Plaintiff's claims are barred, in whole or in part, to the extent they are based on alleged harms resulting from any failure of providers or their patients to read and heed warnings provided with KVK-Tech's products. *See* Restatement (Second) of Torts § 402A, Comment j; Restatement (Third) of Torts: Products Liability § 6. Because KVK-Tech's products are safe for use if such warnings are read and followed, as a matter of law, KVK-Tech's products can be neither defective nor unreasonably unsafe. *Id.*

TWENTY-SECOND AFFIRMATIVE AND ADDITIONAL DEFENSE

22. The Plaintiff's claims are barred, in whole or in part, to the extent they are based on alleged harms resulting from known risks or dangers associated with KVK-Tech's products which are unavoidable even within the scope of prescribed and intended use, but which are reasonable in comparison to the benefits conferred. *See* Restatement (Second) of Torts § 402A, Comment k; Restatement (Third) of Torts: Products Liability § 6.

TWENTY-THIRD AFFIRMATIVE AND ADDITIONAL DEFENSE

23. The Plaintiff's damages, if any, were the direct result of pre-existing medical conditions, idiosyncratic reactions to the medications, and/or were incurred by operation of nature or as a result of circumstances over which KVK-Tech had and continues to have no control.

TWENTY-FOURTH AFFIRMATIVE AND ADDITIONAL DEFENSE

24. The Plaintiff's claims are barred, in whole or in part, by any alteration, modification, or misuse of KVK-Tech's products by prescribing providers, their patients, or any other third parties, for which KVK-Tech cannot be held responsible.

TWENTY-FIFTH AFFIRMATIVE AND ADDITIONAL DEFENSE

25. The Plaintiff's claims are barred to the extent they allege harms resulting from any illicit use or abuse of KVK-Tech's products on the part of the medication users, for which KVK-Tech cannot be held responsible.

TWENTY-SIXTH AFFIRMATIVE AND ADDITIONAL DEFENSE

26. To the extent the Plaintiff asserts claims premised on actual or constructive fraud, false representation, deceit, concealment, or similar alleged misconduct, the Plaintiff fails to state its claims with particularity, including, but not limited to, the time, place, and content of the alleged misrepresentations or concealments, and the specific misrepresentations or concealments of each separate Defendant. 12 Okla. Stat. § 2009(B); Fed. R. Civ. P. 9. To the extent the Plaintiff seeks special items of damages, including, but not limited to, exemplary or punitive damages, the Plaintiff fails to specifically state their nature or provide detail sufficient to inform KVK-Tech of the nature of its claim. *Id.*, § 2009(G).

TWENTY-SEVENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

27. To the extent the Plaintiff seeks to impose liability on KVK-Tech for broad, general statements regarding the value or quality of KVK-Tech's products, which were made to and reasonably understood by providers as opinion, such statements cannot constitute false representations as a matter of law. *See Greene v. Humphrey*, 274 P.2d 535, 537 (Okla. 1960).

TWENTY-EIGHTH AFFIRMATIVE AND ADDITIONAL DEFENSE

28. KVK-Tech's liability, if any, will not result from its conduct, but will result solely from obligations imposed by law. Thus, KVK-Tech is entitled to complete indemnity, express or implied, by other parties.

TWENTY-NINTH AFFIRMATIVE AND ADDITIONAL DEFENSE

29. The Plaintiff's claims seek duplicate or double recovery on the same injury or damage, contrary to Oklahoma law and/or any other state law that may apply.

THIRTIETH AFFIRMATIVE AND ADDITIONAL DEFENSE

30. The Plaintiff is not entitled to attorneys' fees, costs, pre-judgment interest, or post judgment interest.

THIRTY-FIRST AFFIRMATIVE AND ADDITIONAL DEFENSE

31. The Plaintiff seeks the recovery of civil penalties and punitive damages from KVK-Tech for, inter alia, its claims of Nuisance (Count IV, VII), Negligence (Count V, VIII), and Civil Conspiracy (X). To the extent plaintiff seeks punitive, exemplary, or aggravated damages, any such damages are barred because the products at issue, and their labeling, were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301 *et seq.*, as amended, or Section 351, Public Health Service Act (42 U.S.C. § 262), as amended. In addition, the Plaintiff's punitive damages or statutory penalties claims against KVK-Tech:

- a. have no basis in law or fact;
- b. are not recoverable because the FAC's allegations of fact are legally insufficient to support or allow the imposition of punitive damages or statutory penalties on KVK-Tech consistent with the United States Constitution or Oklahoma law and/or that of any other state whose laws may apply;
- c. cannot be sustained because the laws setting forth the standard(s) for determining liability for, and the amount(s) of, punitive damages or statutory penalties fail to give KVK-Tech prior notice of the conduct for which punitive damages or statutory penalties may be imposed and the severity of the penalty that may be imposed, and are void for vagueness

in violation of KVK-Tech's due process rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and Art. II, § 7 of the Oklahoma Constitution and/or that of any other state whose laws may apply;

d. cannot be sustained because any award of punitive damages or statutory penalties exceeding the limits authorized by law would violate KVK-Tech's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and Art. II, § 7 of the Oklahoma Constitution and would be improper under the laws and common law of Oklahoma and/or that of any other state whose laws may apply;

e. cannot be sustained because an award of punitive damages or statutory penalties in this case, combined with any prior, contemporaneous, or subsequent judgments against KVK-Tech for punitive damages or statutory penalties arising from the distribution, supply, marketing, sale, promotion, or use of KVK-Tech's products would constitute constitutionally impermissible multiple punishments for the same wrong and double jeopardy under the Fifth Amendment to the United States Constitution and Art. II, § 21 of the Oklahoma Constitution and/or that of any other state whose laws may apply;

f. cannot be sustained because any award of punitive damages or statutory penalties without the apportionment of the award separately and severally between or among the alleged joint tortfeasors, as determined by the percentage of the wrong(s) allegedly committed by each tortfeasor, would violate KVK-Tech's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and Art. II, § 7 of the Oklahoma Constitution and would be improper under

the laws and common law of Oklahoma and/or that of any other state whose laws may apply;

g. cannot be sustained because any award of punitive damages or statutory penalties is barred by the Due Process Clauses of the United States and Oklahoma Constitution and/or that of any other state whose laws may apply, because due process requires that any award of punitive damages bear a close relationship to appropriate civil fines or penalties established by the legislature, or by administrative agencies under authority delegated by the legislature, and Oklahoma law fails to incorporate this due process requirement, and therefore no award of punitive damages may be constitutionally made under Oklahoma law and/or that of any other state whose laws may apply;

h. cannot be sustained because any award of punitive damages or statutory penalties is barred by the Due Process Clauses of the United States and by the Commerce Clause of the United States Constitution and by principles of federalism embodied in the Constitution and by the Oklahoma Constitution and/or that of any other state whose laws may apply, to the extent that any claim is based on any conduct by KVK-Tech that occurred outside Oklahoma;

i. cannot be sustained because any award of punitive damages or statutory penalties is barred by the Due Process Clauses of the United States and Oklahoma Constitution and/or that of any other state whose laws may apply, to the extent that Oklahoma law and/or the law of any other state whose law may apply permits the introduction of evidence of a defendant's financial condition or "net worth" with respect to the quantum of punitive damages and the introduction of such evidence violates Due Process by inviting the jury to

award an arbitrary amount of punitive damages based on KVK-Tech's status as an industrial enterprise;

j. cannot be sustained because any award of punitive damages or statutory penalties is barred by the Due Process Clauses of the United States and Oklahoma Constitution and/or that of any other state whose laws may apply, because the conduct that is alleged to warrant punitive damages is unrelated to the claimant's harm. Punitive damages may not be awarded to punish and deter conduct that bears no relation to the claimant's harm; and

k. cannot be sustained because subjecting KVK-Tech to punitive damages or statutory damages that are penal in nature without the same protections accorded to criminal defendants would violate KVK-Tech's rights guaranteed without limitation by the Fourth, Fifth, Sixth, and Fourteenth Amendments to the United States Constitution and would be improper under the laws and common law of Oklahoma and/or that of any other state whose laws may apply.

THIRTY-SECOND AFFIRMATIVE AND ADDITIONAL DEFENSE

32. The Plaintiff seeks the recovery of punitive damages from KVK-Tech for allegedly failing to maintain effective controls against prescription opioid diversion and employ a system to identify and report to law enforcement suspicious orders of controlled substances. *See* FAC, ¶166; Nuisance (Count IV, VII), Negligence (Count V, VIII), and Civil Conspiracy (X). The Plaintiff's claims for punitive damages against KVK-Tech cannot be sustained and would violate KVK-Tech's due process and equal protection rights guaranteed by the Fifth and Fourteenth Amendments to the United States Constitution and Art. II, § 7 of the Oklahoma Constitution and/or that of any other state whose laws may apply and would be improper under the laws and common

law of Oklahoma and/or that of any other state whose laws may apply to the extent punitive damages are awarded by a jury that:

- a. is not provided constitutionally adequate standards of sufficient clarity for determining whether to impose, and the appropriate size of, any punitive damages;
- b. is not adequately instructed on the limits of punitive damages set by the applicable principles of deference and punishment;
- c. is not required to make specific findings of fact establishing constitutionally permissible factors;
- d. is not expressly prohibited from awarding or calculating punitive damages based, in whole or in part, on invidiously discriminatory characteristics, including without limitation the residence, financial condition, and corporate state of KVK-Tech;
- e. is permitted to award punitive damages under a standard that is vague and arbitrary or does not define with sufficient clarity the conduct or mental state permitting the imposition of punitive damages;
- f. is not instructed upon, and required to make specific findings of fact with respect to the constitutional factors that govern permissible ratio of punitive damages to compensatory damages;
- g. is not instructed upon, and required to make specific findings of fact with respect to the comparable civil fine that could be imposed on KVK-Tech for the conduct in question;
- h. is not instructed upon, and required to make specific findings of fact with respect to the direct relationship between the conduct and the specific injury suffered by the Plaintiff;
- i. is not properly instructed regarding the Plaintiff's burden of proof with respect to each and every element of a claim for punitive damages; or

j. is not subject to judicial review for reasonableness and furtherance of legitimate purposes on the basis of constitutionally adequate and objective standards.

k. otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991); *TXO Production Corp. v. Alliance Resources Corp.*, 509 U.S. 443 (1993); *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559 (1996); *State Farm Mutual Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003); and *Philip Morris USA v. Williams*, 549 U.S. 346 (2007).

THIRTY-THIRD AFFIRMATIVE AND ADDITIONAL DEFENSE

33. The Plaintiff's damages, if any, are limited to reasonable damages, and exclude unconscionable and grossly oppressive damages contrary to substantial justice. *See* 23 Okla. Stat. § 97. Further, the Plaintiff cannot recover damages in excess of those allowed by the applicable statutory law. In addition and/or in the alternative, Plaintiff's claims are barred to the extent its alleged damages are speculative, uncertain, or hypothetical.

THIRTY-FOURTH AFFIRMATIVE AND ADDITIONAL DEFENSE

34. The Plaintiff's claims against KVK-Tech are barred or limited by the economic loss rule. The Plaintiff alleges purely economic losses in the form of increased spending on opioid prescriptions allegedly resulting from KVK-Tech's challenged conduct. The Plaintiff nonetheless seeks to recover these losses in tort. The economic loss rule bars any such recovery. In addition, and/or in the alternative, any verdict or judgment that might be recovered by Plaintiff must be reduced by those amounts that have already or will in the future, with reasonable certainty, indemnify Plaintiff in whole or in part for any past or future claimed economic loss from any collateral source, such as insurance, social security, workers' compensation, or employee benefit program.

THIRTY-FIFTH AFFIRMATIVE AND ADDITIONAL DEFENSE

35. The Plaintiff's claims, including, but not limited to, any claims inconsistent with discretionary actions by the FDA under the FDCA, are barred, in whole or in part, under the common law doctrine of deference to administrative discretion.

THIRTY-SIXTH AFFIRMATIVE AND ADDITIONAL DEFENSE

36. To the extent the Plaintiff asserts claims dependent solely on alleged violations of federal law, including any claims of a "fraud on the FDA" with respect to KVK-Tech's disclosure of information related to the safety of its products, such claims are barred and should be dismissed. *See Buckman v. Plaintiffs' Legal Claim*, 531 U.S. 341 (2001). In addition and/or in the alternative, to the extent Plaintiff's claims depend on violations of federal law, including any claims of "fraud on the DEA" with respect to KVK-Tech's compliance with statuses or regulations administered and/or enforce by the DEA, such claims are barred and should be dismissed.

THIRTY-SEVENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

37. At all times relevant to the Plaintiff's claims and based upon the state of KVK-Tech's knowledge at those times, KVK-Tech's conduct conformed with the FDCA and the requirements of the FDA, the Controlled Substances Act, and the requirements of the DEA, as well as with all applicable state and federal statutes, regulations, and industry standards. Further, KVK-Tech's methods, standards, and techniques were in conformity with the generally recognized state of the art at the time.

THIRTY-EIGHTH AFFIRMATIVE AND ADDITIONAL DEFENSE

38. The Plaintiff fails to plead that it reimbursed any prescriptions written for an opioid product promoted, sold, or manufactured by KVK-Tech that harmed patients and should not have been written, or that KVK-Tech's allegedly improper conduct caused any provider to write any

ineffective or harmful opioid prescriptions. To the extent the Plaintiff's claims seek to impose liability on KVK-Tech solely on the basis of its proportionate participation in Oklahoma's market for opioid products, and without establishing a causative link between KVK-Tech's specific conduct and the Plaintiff's alleged injuries, such claims are barred under Oklahoma law. *See Case v. Fibreboard*, 743 P.2d 1062, 1064-67 (Okla. 1987).

THIRTY-NINTH AFFIRMATIVE AND ADDITIONAL DEFENSE

39. The Court does not have personal jurisdiction over KVK-Tech and/or Plaintiff's claims may be subject to dismissal due to lack of personal jurisdiction under the Due Process Clause and any potentially applicable state law.

FORTIETH AFFIRMATIVE AND ADDITIONAL DEFENSE

40. The products alleged to be manufactured and/or distributed by KVK-Tech were subsequently modified, altered or changed by others over whom this Defendant had no control.

FORTY-FIRST AFFIRMATIVE AND ADDITIONAL DEFENSE

41. The Plaintiff's claims are barred, in whole or in part, by the doctrines of res judicata, collateral estoppel, and/or issue or claim preclusion.

FORTY-SECOND AFFIRMATIVE AND ADDITIONAL DEFENSE

42. The Plaintiff's claims are barred, in whole or in part, by the terms and effect of any applicable Consent Judgment, including by operation of the doctrines of res judicata, collateral estoppel, issue or claim preclusion, failure to fulfill conditions precedent, failure to provide requisite notice, accord and satisfaction, and compromise and settlement.

FORTY-THIRD AFFIRMATIVE AND ADDITIONAL DEFENSE

43. To the extent the Plaintiff seeks relief for KVK-Tech's alleged conduct occurring before the enactment date of any statutes under which it brings a claim, such claims fail because the statutes do not apply retroactively.

FORTY-FOURTH AFFIRMATIVE AND ADDITIONAL DEFENSE

44. The Plaintiff's claim of unjust enrichment is barred, in whole or in part, because KVK-Tech did not receive and retain any alleged benefit from the Plaintiff. Plaintiff would be unjustly enriched if allowed to recover on any of its claims.

FORTY-FIFTH AFFIRMATIVE AND ADDITIONAL DEFENSE

45. The Plaintiff's claims are barred, in whole or in part, for lack of standing. In addition and/or in the alternative, Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks capacity to bring its claims, including claims maintained, even indirectly, on behalf of its members and/or claims brought as *parens patriae*.

FORTY-SIXTH AFFIRMATIVE AND ADDITIONAL DEFENSE

46. The Plaintiff's claims are barred, in whole or in part, by the Plaintiff's failure to comply with the requirement that it identify each patient and/or Member in whose claim(s) the Plaintiff has a subrogation interest.

FORTY-SEVENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

47. The Plaintiff's claims are barred, in whole or in part, by conflict preemption as set forth in the United States Supreme Court's decisions in *PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011) and *Mutual Pharm. Co. v. Bartlett*, 133 S.Ct. 2466 (2013), and related federal precedent. In addition, to the extent the Nation's state-law claims depends upon allegations that the "Generic Manufacturers can correct the Brand-Name Manufacturers' alleged misrepresentations without

violating the sameness principle,” which would “impose upon the Generic Manufacturers liability for not sending warnings that the Brand-Name Manufacturers had not sent,” such claims are preempted “because it would be impossible for the Generic Manufacturers to comply with both federal law and the supposed state law duty.” (*See* 1:17-md-02804, Doc. Nos. 1499, pp. 34-42; 1680).

FORTY-EIGHTH AFFIRMATIVE AND ADDITIONAL DEFENSE

48. The Plaintiff’s claims are barred, in whole or in part, under the constitutional principles of separation of powers.

FORTY-NINTH AFFIRMATIVE AND ADDITIONAL DEFENSE

49. The laws of the State of Oklahoma may not be applicable to some or all of the Plaintiff’s legal claims and/or damages, including, but not limited to, Plaintiff’s claims being barred in whole or in part, or subject to other limitations, by the Oklahoma Product Liability Act, Plaintiff’s claim of joint liability being contrary to Oklahoma law, including under 12 Okla. Stat. § 13-832, and/or Plaintiff’s claims are limited or barred by Oklahoma law related to successor liability.

FIFTIETH AFFIRMATIVE AND ADDITIONAL DEFENSE

50. Plaintiff’s claim of joint liability is contrary to Oklahoma law as any liability attributed to Defendants should be based on each individual Defendant’s proportional market share.

FIFTY-FIRST AFFIRMATIVE AND ADDITIONAL DEFENSE

51. The laws of the State of Oklahoma may not be applicable to some or all of the Plaintiff’s legal claims and/or damages, including, but not limited to, Plaintiff’s claim of joint

liability being contrary to Oklahoma law, including under 12 Okla. Stat. § 13-832, and/or Plaintiff's claims are limited or barred by Oklahoma law related to successor liability.

FIFTY-SECOND AFFIRMATIVE AND ADDITIONAL DEFENSE

52. The claims asserted in the FAC against KVK-Tech are barred, in whole or in part, by the FDA-approved TIRF REMS Program, including, but not limited to, the requirements imposed on prescribers of TIRF medicines and patients. Plaintiff's claims may be barred, in whole or in part, because neither users nor prescribers relied to their detriment upon any statement by KVK-Tech in determining to use the medications at issue, particularly given the TIRF REMS Access Program, required by the FDA, that mandates prescriber enrollment in order to prescribe TIRF medicines.

FIFTY-THIRD AFFIRMATIVE AND ADDITIONAL DEFENSE

53. Plaintiff's claims are barred, in whole or in part, by the voluntary payment doctrine.

FIFTY-FOURTH AFFIRMATIVE AND ADDITIONAL DEFENSE

54. The claims asserted in the First Amended Complaint are barred because venue is improper and the First Amended Complaint should be dismissed under Rule 12(b)(3) of the Federal Rules of Civil Procedure or, in the alternative, transferred to the proper venue.

FIFTY-FIFTH AFFIRMATIVE AND ADDITIONAL DEFENSE

55. KVK-Tech is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any rule of law or statute of this State or any other state whose substantive law might control the action.

FIFTY-SIXTH AFFIRMATIVE AND ADDITIONAL DEFENSE

56. Any statements in branded or unbranded materials that plaintiff seeks to attribute to KVK-Tech comporting with FDA-approved uses are not misleading, unfair, or deceptive as a matter of law or otherwise actionable.

FIFTY-SEVENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

57. Plaintiff fails to plead any actionable misrepresentation or omission made by or attributable to KVK-Tech. KVK-Tech further states that the representations or statements alleged to have been made were true and accurate at the time made and/or otherwise were made in good faith, with a reasonable belief as to their validity and accuracy and with a reasonable belief that all conduct was lawful. Further, Plaintiff's misrepresentation claims fail because KVK-Tech cannot be held liable for its alleged opinion statements. In addition, and/or in the alternative, Plaintiff cannot obtain relief on its claims based on alleged actions undertaken by KVK-Tech of which KVK-Tech provided notice of all material facts.

FIFTY-EIGHTH AFFIRMATIVE AND ADDITIONAL DEFENSE

58. Any defendant's liability must be limited in accordance with the percentage of fault allocated to it by the ultimate trier of fact and/or law. Each defendant may only be severally liable for any injuries or expenses. Plaintiff's alleged damages are not indivisible but comprise separate and discrete costs.

FIFTY-NINTH AFFIRMATIVE AND ADDITIONAL DEFENSE

59. Plaintiff fails to plead and cannot establish any duty owed to plaintiff by KVK-Tech.

SIXTIETH AFFIRMATIVE AND ADDITIONAL DEFENSE

60. Plaintiff's claims are barred because they violate procedural and substantive due process rights under the Fourteenth Amendment to the U.S. Constitution and Article I, § 1, 2, 16, and 19 of the Constitution of Ohio, and/or any other states whose law may apply, including Oklahoma, and the right to be free from retroactive or ex post facto laws as guaranteed by Article I, § 10 of the United States Constitution and Article II, § 28 of the Constitution of Ohio, and/or any other states whose law may apply, including Oklahoma. KVK-Tech's rights under the Due Process Clause of the U.S. Constitution and applicable state Constitution or statute are further violated by any financial or other arrangement that might distort a government attorney's duty to pursue justice rather than his or her personal interests, financial or otherwise, in the context of a civil enforcement proceeding, including by plaintiff's use of a contingency fee contract with private counsel.

SIXTY-FIRST AFFIRMATIVE AND ADDITIONAL DEFENSE

61. The public nuisance statute of Ohio and/or Oklahoma and/or any other states whose law may apply is unconstitutionally vague. In addition, Plaintiff's common law and public nuisance claims have been abrogated by the Ohio Products Liability Act, Oklahoma law (76 Okla. Stat. § 57.2(G)), and/or any other states' product liability act and/or statutes whose law may apply.

SIXTY-SECOND AFFIRMATIVE AND ADDITIONAL DEFENSE

62. Plaintiff's claims of public nuisance are barred or limited because, among other reasons, no action of KVK-Tech involved interference with real property, illegal conduct perpetrated by third-parties involving the use of an otherwise legal product does not involve a public right against the manufacturer sufficient to state a claim for public nuisance, the alleged

public nuisance would have impermissible extraterritorial reach, and the alleged wrongful conduct of KVK-Tech is too remote from the alleged injury as a matter of law and due process.

SIXTY-THIRD AFFIRMATIVE AND ADDITIONAL DEFENSE

63. Plaintiff's claims against KVK-Tech are barred under the municipal cost recovery rule and/or the free public services doctrine, in that Plaintiff is not entitled to recover governmental expenditures as a matter of law.

SIXTY-FOURTH AFFIRMATIVE AND ADDITIONAL DEFENSE

64. Plaintiff's claims and damages are barred or limited, in whole or in part, by common law, statutory, and state constitutional constraints on the exercise of police powers by a municipality and/or by an Indian tribe and/or sovereign nation.

SIXTY-FIFTH AFFIRMATIVE AND ADDITIONAL DEFENSE

65. As a matter of law, plaintiff is not entitled to a declaratory judgment, injunction, or attorney's fees for these alleged claims. The imposition of injunctive relief and/or civil penalties would be inequitable, particularly in light of defendants' lawful and proper sale of products that are heavily regulated and include an FDA-approved and required warning.

SIXTY-SIXTH AFFIRMATIVE AND ADDITIONAL DEFENSE

66. Plaintiff's claims are barred and should be dismissed under Fed. R. Civ. P. 41(b) and any other applicable rules because plaintiff has refused to comply with the Court's case management orders, including CMO-1, and because plaintiff has refused to identify the allegedly inappropriate, unnecessary, or otherwise improper opioid prescriptions that they contend are at issue and on which they base their claims.

SIXTY-SEVENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

67. Plaintiff's claims are barred by the sophisticated user doctrine. Because of their training and experience, doctors who prescribe opioids know or reasonably should know of the potential risks, and defendants had no duty to warn and cannot be held liable for failing to warn of risks and complications of which members of the relevant medical community knew or should have known.

SIXTY-EIGHTH AFFIRMATIVE AND ADDITIONAL DEFENSE

68. Plaintiff's alleged injury through criminal acts claims fail because there has been no relevant criminal conviction.

SIXTY-NINTH AFFIRMATIVE AND ADDITIONAL DEFENSE

69. Plaintiff's claims are barred, in whole or in part, because the derivative injury rule and the remoteness doctrine bar Plaintiff from recovering payments that it allegedly made on behalf of its members and/or residents to reimburse any expenses for health care, pharmaceutical care and/or other public services.

SEVENTIETH AFFIRMATIVE AND ADDITIONAL DEFENSE

70. Plaintiff's claims are barred, in whole or in part, by the doctrines of acquiescence, settlement, or release. 12 Okla. Stat. § 832(H).

SEVENTY-FIRST AFFIRMATIVE AND ADDITIONAL DEFENSE

71. In the event of liability against KVK-Tech (which liability is specifically denied), a percentage of tortious conduct that proximately caused Plaintiff's injury or loss is attributable to (1) the Plaintiff; (2) other parties from whom Plaintiff seeks recovery and/or (3) persons from whom Plaintiff does not seek recovery in this action (i.e. third party entities and/or individuals)

and the facts will show that any recovery must be otherwise reduced pursuant to 23 Okla. Stat. §§ 13-14.

SEVENTY-SECOND AFFIRMATIVE AND ADDITIONAL DEFENSE

72. The federal RICO statute is unconstitutionally vague.

SEVENTY-THIRD AFFIRMATIVE AND ADDITIONAL DEFENSE

73. Plaintiff's nuisance claims fail because KVK-Tech's activities fall under Oklahoma law's statutory safe harbor for nuisance claims, which forecloses liability for federally-authorized activities. *See* 50 Okla. Stat. § 4.

SEVENTY-FOURTH AFFIRMATIVE AND ADDITIONAL DEFENSE

74. Because Plaintiff is a federally recognized tribe, it lacks standing to pursue any claims under the federal Controlled Substance Act through its Attorney General. *See, e.g., McKesson v. Corp. Hembree*, No. 17-CV-323-TCK-FHM, 2018 WL 340042 (N.D. Okla. Jan. 9, 2018).

SEVENTY-FIFTH AFFIRMATIVE AND ADDITIONAL DEFENSE

75. Plaintiff is a federally recognized tribe that lacks organizational standing to bring any claims in this case.

SEVENTY-SIXTH AFFIRMATIVE AND ADDITIONAL DEFENSE

76. Plaintiff may not be awarded damages for services provided to non-tribal members living outside the boundaries of the Muscogee (Creek) Nation Reservation.

SEVENTY-SEVENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

77. To the extent KVK-Tech followed orders from or performed under contracts with any governmental body, KVK-Tech is immune from suit.

SEVENTY-EIGHTH AFFIRMATIVE AND ADDITIONAL DEFENSE

78. The Oklahoma public nuisance statute is unconstitutionally vague.

SEVENTY-NINTH AFFIRMATIVE AND ADDITIONAL DEFENSE

79. Any damages that Plaintiff may recover against KVK-Tech must be reduced to the extent that Plaintiff is seeking damages for alleged injuries or expenses related to the same user(s) of the subject prescription medications, or damages recovered or recoverable by other actual or potential plaintiffs. Any damages that Plaintiff may recover against KVK-Tech must be reduced to the extent they unjustly enrich Plaintiff.

EIGHTIETH AFFIRMATIVE AND ADDITIONAL DEFENSE

80. Plaintiff's claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and/or setoffs, including, but not limited to 23 Okla. Stat. §§ 9.1, 15, and 12 Okla. Stat. § 832. In addition, and/or in the alternative, Plaintiff cannot obtain relief on its claims based on alleged actions undertaken by KVK-Tech of which KVK-Tech provided notice of all material facts.

EIGHTY-FIRST AFFIRMATIVE AND ADDITIONAL DEFENSE

81. To the extent that Plaintiff relies on letters or other informal guidance from DEA to establish KVK-Tech's alleged regulatory duties, such informal guidance cannot enlarge KVK-Tech's regulatory duties in the absence of compliance by DEA with the requirements by the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.*

EIGHTY-SECOND AFFIRMATIVE AND ADDITIONAL DEFENSE

82. Plaintiff's claims are barred, in whole or in part, because Plaintiff has no private right or cause of action under the relevant laws and regulations.

EIGHTY-THIRD AFFIRMATIVE AND ADDITIONAL DEFENSE

83. Plaintiff's claims are barred in whole or in part, or are subject to other limitations, by the Oklahoma Affordable Access to Health Care Act, 63 Okla. Stat. § 1-1709, et seq.

EIGHTY-FOURTH AFFIRMATIVE AND ADDITIONAL DEFENSE

84. Plaintiff's claims are barred or limited by the Indian Healthcare Improvement Act, the Indian Self-Determination and Education Assistance Act, and/or the Federal Medical Care Recovery Act.

EIGHTY-FIFTH AFFIRMATIVE AND ADDITIONAL DEFENSE

85. In addition and/or in the alternative, Plaintiff's claims are barred, in whole or in part, to the extent that they violate the Dormant Clause of the United States Constitution.

EIGHTY-SIXTH AFFIRMATIVE AND ADDITIONAL DEFENSE

86. Plaintiff's claims are barred by the Doctrine of *in pari delicto*.

EIGHTY-SEVENTH AFFIRMATIVE AND ADDITIONAL DEFENSE

87. Plaintiff's claims are not ripe and/or have been mooted.

EIGHTY-EIGHTH AFFIRMATIVE AND ADDITIONAL DEFENSE

88. Plaintiff's claims are barred because Plaintiff is not the real party and/or parties in interest.

EIGHTY-NINTH AFFIRMATIVE AND ADDITIONAL DEFENSE

89. In addition and/or in the alternative, Plaintiff's claims are barred, in whole or in part, for failure to exhaust administrative or tribal remedies.

NINETIETH AFFIRMATIVE AND ADDITIONAL DEFENSE

90. Plaintiff's claims are barred to the extent KVK-Tech has valid defenses which would bar recovery by those persons on whose behalf Plaintiff seeks recovery. In addition and/or

in the alternative, Plaintiff's claims are subject to all defenses that could be asserted if Plaintiff's claims were properly made by individuals on whose behalf Plaintiff seeks to recover. KVK-Tech asserts all applicable defenses under Fed. R. Civ. P. 8(c) and 12(b) and/or 12 Okla. Stat. § 2012 (2019), as investigation and discovery proceeds. KVK-Tech further adopts by reference any additional applicable defense pleaded by any other Defendants not otherwise pleaded herein.

NINETY-FIRST AFFIRMATIVE AND ADDITIONAL DEFENSE

91. Defendant, KVK-Tech, specifically denies each and every allegation set forth in the Plaintiff's First Amended Complaint unless expressly admitted to herein. KVK-Tech hereby gives notice it intends to rely upon any other defenses that may become available or apparent during discovery or investigation in this matter and hereby reserves its right to amend its First Amended Answer and to assert any such additional defenses.

REQUEST FOR JURY TRIAL

Defendant KVK-Tech, Inc. respectfully requests a trial by jury (12) on all issues so triable.

BIFURCATED TRIAL DEMAND

If the Nation is permitted to proceed upon claims for punitive damages, exemplary damages, or penalties, such claims must be bifurcated from the remaining issues for trial, and Defendant KVK-Tech, Inc. reserves the right to seek such bifurcation.

WHEREFORE, having fully answered, Defendant KVK-Tech Inc. respectfully requests that the Court deny the relief requested by Plaintiff The Muscogee (Creek) Nation and dismiss Plaintiff The Muscogee (Creek) Nation's First Amended Complaint, with prejudice, that Plaintiff The Muscogee (Creek) Nation go hence at its costs, and for all other and further relief as this Court deems just and proper.

Dated: August 15, 2019

Respectfully submitted,

By: /s/ Thomas E. Rice

Thomas E. Rice *

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**denotes national trial counsel who will seek pro
hac vice admission*

**ATTORNEYS FOR DEFENDANT
KVK-TECH, INC.**

CERTIFICATE OF SERVICE

I hereby certify that on August 15, 2019, a copy of the foregoing was filed electronically.
Notice of this filing will be sent to all parties by operation of the Court's electronic filing system.
Parties may access this filing through the Court's system.

/s/ Thomas E. Rice